



PATENT
930008-2003

REMARKS

Reconsideration and withdrawal of the objections to and rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

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I. STATUS OF CLAIMS AND FORMAL MATTERS

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Claims 52-69 are now pending. Claims 3-14 and 24-51 were cancelled, the Title and the Sequence Listing amended, and an Abstract added, without prejudice. Applicants reserve the right to pursue cancelled subject matter in a continuing and/or divisional application.

Attached hereto is a marked up version of the changes made to the Title by the present amendment. This attachment is captioned "Version with Markings Showing Changes Made." Further, attached hereto is an Abstract on a separate page.

No new matter is added by this amendment.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Support for new claims 52-69 is found throughout the specification and from the cancelled claims.

II. OBJECTIONS TO THE SEQUENCE LISTING

The sequence listing was objected to for allegedly reciting redundant sequences. The objection is traversed.

The deletion of SEQ ID NOS. 13, 14, 15 and 19, without prejudice, has rendered the rejection moot.

Consequently, reconsideration and withdrawal of the objections are respectfully requested.

III. OBJECTIONS TO THE CLAIMS

Claims 7, 8, 28 and 29 were objected to under 37 C.F.R. §1.75 as allegedly being in improper dependent form. The rejection is traversed.

The cancellation of the pending claims and addition of new claims 51-69 have rendered the objection moot.

Consequently, reconsideration and withdrawal of the objections are respectfully requested.

IV. OBJECTIONS TO THE SPECIFICATION

The specification was objected to for not having an abstract; for allegedly having a non-descriptive title; and for allegedly introducing new matter by the inclusion of SEQ ID NOS. 6-12 and 14-18 in the October 15, 1999 Amendment. The objections are traversed.

The addition of an Abstract and the amendment to the Title, without prejudice, have rendered the objections to the Abstract and the Title moot.

Applicants, however, respectfully disagree with the allegation that new matter was introduced by the October 15, 1999 Amendment. This application is a 35 U.S.C. §371 application of PCT/EP98/04510, wherein said PCT/EP98/04510 recited Figures 1-10 to which SEQ ID NOS. 6-12 and 14-18 correspond. The Examiner is respectfully reminded that for purposes of Section 371, that which is disclosed in the PCT application carries over into the U.S. application. Thus, Figures 1-10 find support in the instant application, and assigning SEQ ID NOS to these figures is no different than assigning SEQ ID NOs to sequences that originally existed in the instant specification. Therefore, no new matter has been introduced.

Consequently, reconsideration and withdrawal of the objections are respectfully requested.

V. 35 U.S.C. §112, SECOND PARAGRAPH, REJECTIONS

Claims 3-9, 11-14, 24-30 and 32-33 were rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. The rejection is traversed.

The cancellation of these claims, and the addition of claims 52-69, without prejudice, have rendered the instant rejection moot.

Consequently, reconsideration and withdrawal of the rejections are respectfully requested.

VI. 35 U.S.C. §112, FIRST PARAGRAPH, REJECTIONS

Claims 24-26 and 3-9, 11-14, 24-30 and 32-33 were rejected under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was allegedly not described in the specification in such a way as to reasonably convey that Applicants had possession of the invention. The rejection is traversed.

The cancellation of these claims, and the addition of claims 52-69, without prejudice, have rendered the instant rejection moot.

Consequently, reconsideration and withdrawal of the rejections are respectfully requested.

VII. 35 U.S.C. §102 REJECTIONS

Claims 3-9 and 24-29 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Canadian Patent No. 2,194,411 to Kunsch et al. The rejection is traversed.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Bariant Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985). Applying the law to the instant facts, the document relied upon by the Office Action does not disclose, suggest or enable Applicants' invention.

The instant invention is directed to, *inter alia*, a kit for the selective analytical detection of *Staphylococcus aureus*. Example 1 shows that *Staphylococcus aureus* can be selectively discriminated from other *Staphylococcus* species, as well as from species of other genera. Such discrimination is possible by, for example, using non-conserved DNA regions. Prior to the instant invention, the art did not provide for defined non-conserved DNA regions for a discrimination of *Staphylococcus aureus*.

Kunsch et al. does not anticipate the instant invention as Kunsch et al. does not teach or suggest, *inter alia*, the discrimination of *Staphylococcus aureus* from other *Staphylococcus* species. Applicants also disagree with the contention in the Office Action that many of the sequences allegedly recited by Kunsch et al. meet the limitations of the instant claims. Kunsch et al. does not teach or suggest SEQ ID NO. 1. For example, SEQ ID. NO. 3803 comprises more than just SEQ ID NO. 1, and there is no teaching or suggestion that SEQ ID NO. 3803 can be used to differentiate *Staphylococcus aureus* from other *Staphylococcus* species or species of other genera. Further, SEQ ID NO. 4725 differs from instant SEQ ID NO. 1 in at least

nucleotides 1 to 105. Thus, contrary to SEQ ID. NO. 1, SEQ ID NO. 4725 does not belong to the 23S/5S intergenic region. Similarly, nowhere in Kunsch et al. is there any teaching or suggestion that SEQ ID NO. 5094 could be used to differentiate *Staphylococcus aureus* from other *Staphylococcus* species or species of other genera.

The Office Action appears to be relying upon the doctrine of inherency to underscore its rejections of the claims. However, it is not enough to merely allege that because Kunsch et al. recites 5,191 sequences and polynucleotides of *S. aureus* that it must "inherently" speak to the instantly claimed invention. The reference must disclose or suggest the properties of the claimed invention for inherency to attach. According to *In re Rijckaert*, 9 F.3d 1531, 1957 (Fed. Cir. 1993), "such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection." The Federal Circuit is clear that "'inherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency].'" *Continental Can Company v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), *citing to In re Oelrich*, 666 F.2d 578, 581-582 (C.C.P.A. 1981). Indeed, "before a reference can be found to disclose a feature by virtue of its inherency, one of ordinary skill in the art viewing the reference must understand that the unmentioned feature at issue is *necessarily* present in the reference." *SGS-Thomson Microelectronics, Inc. v. International Rectifier Corporation*, 31 F.3d 1177 (Fed. Cir. 1994) (emphasis in original).

Applying the law to the instant facts, the document relied upon in the Office Action does not inherently teach, disclose or suggest Applicants' invention. For example, Kunsch et al. does not even hint at differentiating *Staphylococcus aureus* from other *Staphylococcus* species or species of other genera.

Consequently, reconsideration and withdrawal of the Section 102 rejections are respectfully requested.

CONCLUSION

By this Amendment, the instant claims should be allowed; and this application is in condition for allowance. Favorable reconsideration of the application, withdrawal of the rejections and objections, and prompt issuance of the Notice of Allowance are, therefore, all earnestly solicited.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE TITLE:

On page 1, line 1, kindly amend the title, without prejudice, to read as follows:

[Nucleic acid molecule, kit and use] Analytical Detection of *Staphylococcus aureus*.

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